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K022552

Section 3
Coamatic® LR Antithrombin - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
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Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

August 1, 2002

Name of the Device:

Coamatic® LR Antithrombin

Classification Name(s):

864.7060	Antithrombin III Assay	Class II
81JBQ	Antithrombin III Quantitation	

Identification of Predicate Device(s):

K994238	IL Test™ Liquid Antithrombin

Description of the Device/Intended use(s):

Coamatic® LR Antithrombin is intended for the quantitative determination of the heparin cofactor activity of antithrombin (AT) in human citrated plasma. All components of the kit are in liquid formulation (LR = Liquid Reagents).

Antithrombin is the most important natural inhibitor of the coagulation cascade. By inhibiting the coagulation proteases, especially thrombin, factor Xa and factor IXa, antithrombin prevents uncontrolled coagulation and thrombosis. Plasma is incubated with an excess of Factor Xa (FXa) in the presence of heparin. The residual activity of FXa is determined by the rate of hydrolysis of the chromogenic substrate S-2772. The pNA release measured at 405 nm is inversely proportional to the AT level in the range 15-125% of normal plasma.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

Coamatic® LR Antithrombin is substantially equivalent in performance to the predicate device: IL Test™ Liquid Antithrombin

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Summary of Performance Data:

Method Comparison

In a method comparison study evaluating 61 citrated plasma samples with Antithrombin levels ranging in value from 8.6% to 121.5% AT activity, the correlation statistics for Coamatic® LR Antithrombin on an ACL Futura versus the predicate device on an ACL 9000 are shown below:

System	Slope	Intercept	r	Reference Method
ACL Futura	1.011	0.4889	0.995	IL Test™ Liquid AT on ACL 9000

Precision

Within run and total precision assessed over multiple runs using three levels of control plasma gave the following results:

ACL Futura

Mean (% AT)	CV% (Within run)	n	CV% (Total)	n
114	1.96	6	3.52	60
59	6.21	6	6.43	60
29	8.45	6	11.09	60

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 27 2002

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421-3125

Re: k022550
Trade/Device Name: Coamatic® LR Antithrombin
Regulation Number: 21 CFR § 864.7060
Regulation Name: Antithrombin III Assay
Regulatory Class: II
Product Code: JBQ
Dated: August 1, 2002
Received: August 2, 2002

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K022550

Device Name: Coamatic® LR Antithrombin

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022550

✓ Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)